Unverdorben, Martin

From: Michael Szwanek (402)437-4880 [Michael.Szwanek@mdsps.com]
Sent: Wednesday, February 19, 2003 11:46 AM
To: jan.oey@pmusa.com; Hans-Juergen.Roethig@pmusa.com; martin.unverdorben@pmusa.com; qiwei.liang@pmusa.com; bettie.l.nelson@pmusa.com; paul.mendes@pmusa.com
Cc: Paul Johnson; Megan McCrory; Kimberly Prchal; Steve Hambek; Robert Earl
Subject: EHCJLI/04/03 Menthol

Sensitivity: Confidential

AA04271_D2_19FEB03_Philip Morr...

AA04271_19FEB03 ATTACHMENTS_Ph.

All,

Attached is draft two protocol and selected attachments dated Feb 19, 2003 for the upcoming 10-day Menthol study for your review. I have incorporated all changes discussed since the original first draft that was released on Jan 31, 2003. I would appreciate a thorough review as many changes have been made since the first draft including the addition of another group which affects all sections of the protocol including objectives and stats. I assume that you will also need to have the Philip Morris legal team review as well.

There is a high possibility that the IRB date for this study may change from March 11 to March 7. If this happens, then I'll need all documents (protocol, attachments, ICF) final and ready for submission by Friday, Feb 28, 2003. We will begin modifying the ICF immediately and have for you before the end of the week.

Thanks,

Michael F. Szwanek, Pharm D., MBA
Section Head, Protocol Development and ICFs
MDS Pharma Services - Lincoln, NE
michael.szwanek@mdsps.com
(402) 437-4880

PM3005219243

Source: https://www.industrydocuments.ucsf.edu/docs/knlj0001

Unverdorben, Martin

From: Unverdorben, Martin
Sent: Tuesday, February 18, 2003 6:47 PM
To: Roethig, Hans
Subject: Accepted: Updated: SCoR Data Analysis

PM3005219244

Source: https://www.industrydocuments.ucsf.edu/docs/knlj0001

Unverdorben, Martin

From: Unverdorben, Martin
Sent: Friday, February 14, 2003 3:54 PM
To: 'Megan McCrory'
Subject: RE: Accord long term AEs

Sensitivity: Confidential

Martin Unverdorben
Md PhD (E-m...

Thank you,

Martin

-----Original Message-----
From: Megan McCrory [mailto:Megan.McCrory@mdsps.com]
Sent: Friday, February 14, 2003 12:57 PM
To: Bettie.L.Nelson; martin unverdorben
Cc: Kimberly Prchal; Mary Hetrick
Subject: Accord long term AEs
Sensitivity: Confidential

Bettie,

I did a quick analysis of the most common AEs seen on the long term Accord study in Lincoln. I only looked at AEs that started after they were randomized through the 3 month report. Here is what I found:

# of Occurances	AE	Average Severity	Relationship
4	Backache	Moderate	Unrelated
5	Cough	Mild	UNK
12	Headache	Mild	Unlikely/Remote
7	Heartburn	Moderate	Unlikely/Remote
8	Sinus (ache, congestion, etc)	Moderate	Unlikely/Remote

Dr. Kisicki has not finished all of the relationship coding, so I denoted the trend of those that he had coded. The UNK is because he had not yet coded any of the cough AEs.

Please let me know if you would like further information.

Best regards,
Megan

PM3005219245

Source: https://www.industrydocuments.ucsf.edu/docs/knlj0001

Unverdorben, Martin

From: Unverdorben, Martin
Sent: Friday, February 14, 2003 3:53 PM
To: Williams, David L.
Subject: RE: 310/2002: Importation of trial products

The only attachment to this email is the vCard containing my signature. Is that your problem?

Regards,

Martin

Martin Unverdorben
Md PhD (E-m...

-----Original Message-----
From: Williams, David L.
Sent: Friday, February 14, 2003 1:29 PM
To: Unverdorben, Martin
Subject: RE: 310/2002: Importation of trial products

Martin,

For some reason I caanot upen your attachments. This effects the last few e-mails you have sent. I still have the old Windows 95 software, so maybe that is the problem. Could you please resend as a different attachment or maybe give me a suggestion on how to proceed.

Thank you,

David

-----Original Message-----
From: Unverdorben, Martin
Sent: Friday, February 14, 2003 9:11 AM
To: 'Marlize De Lange'; King, Valerie A.; Wrenn, Sue; Burton, Douglas A.; Williams, David L.; Werley, Mike; Werley, Michael S
Subject: RE: 310/2002: Importation of trial products

<?xml version="1.0" ?>
Marlize,

Valerie will respond to you as well.

we shall ship 3,600 cigs of each brand and 10 Activated Heaters along with 10 spare battery packs.

Regards,

Martin

-----Original Message-----
From: Marlize De Lange [mailto:Marlize.Delange@farmovs-parexel.com]
Sent: Friday, February 14, 2003 8:54 AM
To: martin.Unverdorben@pmusa.com; valerie.A.King@pmusa.com
Cc: anina.vanderbijl@farmovs-parexel.com
Subject: 310/2002: Importation of trial products

Source: https://www.industrydocuments.ucsf.edu/docs/knlj0001

Unverdorben, Martin

From: Unverdorben, Martin
Sent: Thursday, February 13, 2003 5:35 PM
To: Roethig, Hans
Subject: Accepted: Updated: SCoR Data Analysis

PM3005219247

Source: https://www.industrydocuments.ucsf.edu/docs/knlj0001